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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,702	03/13/2007	Louise Edwards	5998-0507PUS4	2415

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BIRCH, STEWART, KOLASCH & BIRCH, LLP
P.O. BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
SHAMEEM, GOLAM M	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
04/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,702	EDWARDS ET AL.	
	Examiner	Art Unit	
	Golam M. M. Shameem	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/18/07; 03/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

This application is a 371 of PCT/US05/04774 02/15/2005 is acknowledged.

Status of Claims

Claims 1-18 are currently pending in the application.

Claims 1-11 and 18 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 06/18/2007, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group IV, (which includes claims 12-17, drawn to a method for the treatment of a disorder) with traverse is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a). Therefore, the requirement for restriction is still deemed proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The expressions "mGluR5 receptor-mediated disorders" (claim 12, lines 1-2, page 401), "neurological disorder" (claim 13, line 1, page 401), "neurodevelopmental disorders" (claim 17, line 8, page 402 and all other occurrences, if any), and "cardiovascular diseases" (claim 17, line 12, page 402 and all other occurrences, if any) which broaden the enabling disclosure because it is unclear what kind of "mGluR5 receptor-mediated disorders", "neurological disorder", "neurodevelopmental disorders", and "cardiovascular diseases" the applicant is intending to encompass with these expressions and therefore, the specification fails to provide sufficient support to treat all the wide range of mGluR5 receptor-mediated disorders, neurological disorder, neurodevelopmental disorders etc associated with Central Nervous System (CNS). The type or mode of action and functionality of mGluR5 receptor-mediated disorders and the other diseases associated with this receptor and CNS which are not defined in the claims or anywhere in the specification so as to ascertain the metes and bounds of the claimed subject matter.

The recitations "mGluR5 receptor-mediated disorders", "neurological disorder", "neuron-developmental disorders", and "cardiovascular diseases, which are not described in such a way as to satisfy the statutory requirements within the purview of 35 U.S.C. § 112 first paragraph,

because the specification does not provide essential description to carry out the invention and thus lacks enablement as well. As stated in the MPEP 2164.01 (a), there are many factors [1) The nature of the invention, 2) The state of the prior art, 3) The level of ordinary skill in the art, 4) The level of predictability in the art, 5) The amount of direction and guidance provided by the inventor, 6) The existence of working examples, 7) The breadth of the claims, and 8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure (*In re Wands, 8 USPQ 2d 1400, 1404 (CAFC, 1988)*] to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." Therefore, it is not likely that **a single compound** would be predicted to be able to treat all kinds of diverse CNS and other receptor-mediated diseases as claimed in the instant application. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed methods of use without undue experimentation, see *In re Armbruster 185 USPQ 152 CCPA 1975.* Thus, the specification fails to provide sufficient support of the broad use of the method claims 12-17 to treat all the clinical conditions associated with CNS and other receptor-mediated diseases. Therefore, it is suggested to amend the claims with in the context and scope of the claims [such as, deleting those expressions and limiting specific type of mGluR5 receptor-mediated disorders that actually contemplated in the specification and / or incorporating limitations of claims 14-17 into claim 12 that have enough support, e,g, '--A method for the treatment of a disorder comprising administering to a mammal in need thereof wherein said disorder is selected from the group consisting of [as selected disorders listed in claim 17] ---' etc in order to overcome the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-17 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 12-17 of co-pending Application No. 11/840,952 (US '952), over claims 12-17 of co-pending Application No. 11/840,953 (US '953), over claims 12-17 of co-pending Application No. 11/840,954 (US '954), and also and over claims 12-17 of co-pending Application No. 11/840,955 (US '955). Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims are drawn to the same art recognized subject matter. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The pharmaceutical composition and the method of uses of a compound taught by all the above co-pending applications are similar to instant application because a reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art to use the compounds and compositions to treat mGluR5 receptor-mediated disorders at the time of the invention was made, since co-pending Application No. US '952, US '953, US

'954 and US '955, all teach the generic pharmaceutical composition and the method of uses of a compound which are similar to the instantly claimed invention.

The subject matter claimed in the instant application is fully disclosed and covered by co-pending Application No. US '952, US '953, US '954 and US '955. Therefore, the disclosure of prior art that teach many permutation and combination of formula No. 943-1006 for treating mGluR5 receptor-mediated disorders, which would easily place Applicants invention in possession of the public at the time of Applicants invention was filed. The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin,* 141 USPQ 814 (1964). The claimed compositions and methods of use are so closely related structurally to the homologous and /or analogous compositions and methods of use of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Therefore, in looking at the instantly claimed pharmaceutical composition and the methods of use as a whole, the claimed compositions and methods of use would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Objections

The expression **"prevention"** must be deleted from claim 12 (lines 1-2, page 401, and all other occurrences of claims 12-17, if any) because the term is undefined by Applicant's disclosure and also it is not enabled.

Claim 12-17 are objected to as being dependent upon non-elected base claim, such as claim 1. The claim should be rewritten as an independent form including all of the limitations of the base claim and any intervening claims.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem/

Primary Examiner
Art Unit 1626
Technology Center 1600